

Register a notice of the receipt of any test data submitted under this Agreement. Subject to TSCA section 14, the notice shall provide information similar to that described in TSCA section 4(b). Except as otherwise provided in TSCA section 14, such data will be made available for examination by any person.

Finally, the FIG understands that failure to conduct the testing according to the specified protocol(s) and failure to follow Good Laboratory Practices may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to promulgate a test rule or otherwise require further testing.

VI. References

- (1) Fluoroalkene Industry Group. Unpublished Report on Potential Exposure to Vinyl Fluoride During Manufacture of Monomer Vinyl Fluoride. Submitted to USEPA June 26, 1981.
- (2) Fluoroalkene Industry Group. Unpublished Report on Vinylidene Fluoride (VDF) Exposure. Submitted to USEPA June 26, 1981.
- (3) Halocarbon Products Corporation. Letter from L. Ferstandig to A. Keller, June 25, 1982.
- (4) Halocarbon Products Corporation. Letter from L. Ferstandig to A. Keller, April 27, 1981.
- (5) TSCA Chemical Substances Inventory (EPA 1977).
- (6) Fluoroalkene Industry Group. Unpublished Report on Potential Exposure to Tetrafluoroethene During Manufacture of Monomer Tetrafluoroethene. Submitted to USEPA August 13, 1981.
- (7) Chemical Hazard Information Profile Vinylidene Fluoride; Vinyl Fluoride. January 30, 1978.
- (8) Coffey, S., ed. "Rodd's Chemistry of Carbon Compounds", 2nd Ed. Vol. 1, Part A. Amsterdam: Elsevier. 1964.
- (9) Hawley, G.G. "The Condensed Chemical Dictionary", 10th ed. New York: Van Nostrand Reinhold. 1981.
- (10) Fluoroalkene Industry Group. Comments on Fluoroalkene ANPR (Docket No. 42002) January 26, 1982.
- (11) NIOSH. Natl. Inst. Occupational Safety and Health. Criteria for a recommended standard: occupational exposure to vinyl halides. Unpublished. Washington, D.C.: NIOSH, U.S. Dept. Health, Education, and Welfare. 1979.
- (12) NIOSH (National Institute for Occupational Safety and Health). Vinyl Fluoride Industrial Hygiene Survey Report. October 1977.
- (13) NIOSH/OSHA (National Institute for Occupational Safety and Health/ Occupational Safety and Health Administration). Current Intelligence Bulletin 28. Vinyl Halides Carcinogenicity. September 21, 1978. DHEW (NIOSH) Publication No. 79-102.
- (14) NIOSH. SIC/NOSH Survey. Computer printout of survey covering 1972-74. Retrieved by USEPA 1980.

(15) Morrison, R.T. Boyd, R.N. "Organic Chemistry", 2nd Edition. Boston: Allyn and Bacon. 1966.

(16) The Society of the Plastics Industry, Inc. Ninety-Day Inhalation Toxicity Study with Tetrafluoroethylene (TFE) in Rats and Hamsters. Haskell Laboratory Report No. 208-82. July 20, 1982.

(17) Fluoroalkene Industry Group. Proposed Fluoroalkene Testing Program General Study Plan. June 30, 1982.

VII. Public Record

EPA has established a public record for this decision not to initiate testing under section 4 (docket number OPTS-42002A). This record includes:

- (1) Federal Register Notice designating the fluoroalkenes to the priority list.
- (2) Communications with industry related to the FIG program, consisting of letters, contact reports of telephone conversations, and meeting summaries.
- (3) FIG program.
- (4) Study plans.
- (5) Published and unpublished data.
- (6) Federal Register ANPR requesting comments on the proposed testing, and comments received.

The record, containing the basic information considered by the Agency in developing this decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday except legal holidays in the OPTS reading room, E-107, 401 M Street, SW, Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information. (Sec. 4, 90 Stat. 2003; 15 U.S.C. 2601).

Dated: May 28, 1984.

William D. Ruckelshaus,
Administrator.

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[OPTS-42040A; TSH-FRL 2578-1]

Tris(2-Ethylhexyl) Trimellitate Decision To Adopt Negotiated Testing Program

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: In the Federal Register of November 14, 1983, EPA announced a preliminary decision not to initiate rulemaking under section 4(a) of the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of tris(2-ethylhexyl) trimellitate (TOTM) [CAS No. 3319-31-1] pending consideration of public comments on a testing proposal submitted to EPA by the Trimellitate Esters Panel (TEP), a group formed under the sponsorship of the Chemical Manufacturers

Association (CMA). No public comments were received and the Agency finds no reason to alter its preliminary decision and is not proposing a section 4(a) rule to require environmental or health effects testing of TOTM.

FOR FURTHER INFORMATION CONTACT:

Edward A. Klein, Director, TSCA Assistance Office (TS-799), Office of Toxic Substances, Rm. E-543, 401 M Street SW., Washington, D.C. 20460, Toll Free: (800-424-9065). In Washington, D.C.: (554-1404). Outside the USA: (Operator-202-554-1404).

SUPPLEMENTARY INFORMATION:

I. Background

In the Federal Register of November 14, 1983 (48 FR 51842), the Agency announced a preliminary decision not to propose a rule under section 4(a) of the Toxic Substances Control Act (TSCA) to require environmental or health effects testing of tris(2-ethylhexyl) trimellitate (TOTM). This decision was based on the Agency's evaluation of the existing data on TOTM, the expected exposure pattern for TOTM and the tentative acceptance of a testing proposal submitted by the Trimellitate Esters Panel (TEP), a group formed under the sponsorship of the Chemical Manufacturers Association (CMA).

A draft of TEP's testing proposal was included in the public record (docket number OPTS-42040). The Agency requested comments on both its tentative decision not to require testing of TOTM and on the proposed testing scheme.

II. Summary of Ongoing and Planned Testing Programs

The Trimellitate Esters Panel (TEP) has presented to EPA a proposal for testing TOTM for health effects, environmental effects, and chemical fate. The tests will be modeled after the TSCA testing guidelines. The TEP has provided the Agency with preliminary laboratory selection information and a proposed testing schedule predicated on final program acceptance by the Agency in June 1984. The TEP proposal for TOTM includes the following tests:

1. *Mutagenicity.* To characterize further the genetic activity of TOTM, the TEP will perform an unscheduled DNA synthesis assay in primary rat hepatocytes and a Chinese Hamster Ovary Hypoxanthine Guanine Phosphoribosyl Transferase Forward Mutation assay. These studies are scheduled to begin in July, 1984, and be completed (final report submitted) in January 1985.

2. *Chemical disposition and metabolism.* Eastman Kodak Company, a member company of the TEP, is conducting an *in vivo* metabolism study using TOTM. When results and conclusions of this work are available, they will be submitted to the Agency. On February 6, 1984, the Eastman Kodak Company submitted to the Agency final reports on the mutagenicity of urinary metabolites and the *in vitro* metabolism of TOTM. The anticipated completion date for the *in vivo* metabolism study is May, 1984.

3. *Twenty-eight-day feeding study.* The TEP will conduct a 28-day feeding study which will include examination of major organs and neurological tissues, full clinical chemical and hematological profiles, and an investigation of peroxisome induction and hypolipidemia. This study will begin in July, 1984 with completion scheduled for June, 1985.

4. *Physical-chemical properties.* The TEP will develop an analytic method for measuring TOTM in water. The TEP will then determine the maximum solubility of TOTM in water and the octanol-water partition coefficient of TOTM. Methodology development will begin in July, 1984 and be completed by October, 1984. Determinations using this method will be completed in February, 1985.

5. *Biodegradation.* TOTM will be tested in a shakeflask biodegradation test to determine the rate of parent compound disappearance, CO₂ evolution, and the percentage of carbon converted to CO₂. This study is planned from February through June, 1985.

6. *Toxicity to aquatic invertebrates.* A 21-day reproduction study in *Daphnia magna* will be conducted to assess the environmental impact of TOTM. Acute toxicity data will be generated from the range-finding studies done in preparation for this study. This study is planned from March through September, 1985 with final reports submitted by October, 1985.

After review of results of the base set tests by the TEP and EPA personnel, EPA will determine if further studies, such as subchronic and chronic studies, are necessary.

III. GLP's and Other Provisions

Program reviews will be conducted by EPA at appropriate intervals throughout the program to assess the need for additional testing of TOTM. Should TEP fail to make a good faith effort to adhere to its testing schedule outlined above, EPA may initiate rulemaking to require testing.

The TEP has furnished EPA with the names and addresses of the laboratories

conducting the tests under this agreement. The TEP has also agreed to adhere to the Good Laboratory Practice Standards promulgated by the U.S. Environmental Protection Agency as published in the Federal Register of November 29, 1983 (48 FR 53922). The TEP has agreed to permit laboratory inspections and study audits in accordance with the provisions outlined in TSCA section 11 at the request of authorized representatives of the EPA for the purpose of determining compliance with this agreement. These inspections may be conducted for purposes which include verification that testing has begun, that schedules are being met, that reports accurately reflect the underlying raw data and interpretations and evaluations thereof, and that the studies are being conducted according to Good Laboratory Practice provisions.

The TEP has further agreed that all raw data, documentation, records, protocols, specimens, and reports generated as a result of each study will be retained for at least 10 years from the date of publication of the acceptance of any protocols by EPA and made available during an inspection or submitted to EPA if requested by EPA or its designated representative. The TEP understands that the Agency plans to publish quarterly in the Federal Register a notice of the receipt of any test data submitted under this agreement. Subject to TSCA section 14, the notice will provide information similar to that described in TSCA section 4(d). Except as otherwise provided in TSCA section 14, any data submitted will be made available by EPA for examination by any person.

Finally, the TEP understands that failure to conduct the testing according to the specified protocols and failure to follow Good Laboratory Practice procedures may invalidate the tests. In such cases, a data gap may still exist, and the Agency may decide to require further testing.

IV. Public Comment on TEP's Proposed Testing Program for TOTM

The Agency has received no public comment on EPA's proposed decision not to test TOTM and on the TEP's proposed testing scheme for this chemical.

V. Decision To Adopt Negotiated Testing Program

The Agency currently believes that this testing program will provide sufficient data to reasonably determine or predict the health and environmental effects of TOTM and is adopting this negotiated testing program in lieu of

initiating rulemaking under TSCA section 4.

Depending on the results of the preliminary data review in this negotiated testing agreement, the Agency may determine that additional health and environmental effects tests should be conducted. If, having evaluated the data developed during the negotiated testing program, the Agency determines that additional testing should be conducted, EPA reserves the right to propose a test rule to obtain the additional test data.

VI. Public Record

EPA has established a public record for this decision not to pursue testing under section 4 [docket number OPTS-42040]. This record includes:

(1) Federal Register notice designating TOTM to the priority list (47 FR 54624) and all comments on TOTM reviewed in response thereto.

(2) Communications with industry on the testing proposal consisting of letters, contact reports of telephone conversations, and meeting summaries.

(3) Testing proposals and protocols.

(4) Published and unpublished data.

(5) Federal Register notice requesting comment on the negotiated testing proposal and comments received in response thereto (48 FR 51842).

The record, containing the basic information considered by the Agency in developing the decision, is available for inspection from 8:00 a.m. to 4:00 p.m. Monday through Friday, except legal holidays, in Room E-107, 401 M St. SW, Washington, D.C. 20460. The Agency will supplement this record periodically with additional relevant information received.

(Sec. 4, 90 Stat. 2003 (15 U.S.C. 2601))

Dated: May 28, 1984.

William D. Ruckelshaus,
Administrator.

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[OPPE-FRL 2598-3]

Agency Information Collection Activities Under OMB Review

AGENCY: Environmental Protection Agency.

ACTION: Notice.

SUMMARY: Section 3507(a)(2)(B) of the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 et seq.) requires the Agency to publish in the Federal Register a notice of proposed information collection requests (ICRs) that have been forwarded to the Office of